

### **Remarks**

The present invention as defined by the claims is directed to a packaged medicinal product having extended shelf-life comprising a medicinal preparation; and a plastic container having a fluorinated barrier layer on a surface of the body wall, wherein the body of the container is filled with the medicinal preparation.

Claims 1-33 are pending in this application. Claims 13, 18, 23 and 29 are amended herein. Basis for these amendments is found throughout the specification as originally filed. No new matter has been added.

Applicants respectfully requests reconsideration and withdrawal of the outstanding objections and rejections in light of the foregoing amendments and following remarks. For the reasons that follow, Applicants believe that all claims are now in condition for allowance.

### **Drawings**

Submitted herewith is a drawing in compliance with 37 CFR 1.81, which illustrates the subject matter of this application. Basis for this drawing is found throughout the specification as originally filed. No new matter has been added.

### **Claim Rejections - 35 USC § 112**

The Office Action has rejected claims 13, 18, 23 and 29 under 35 USC §112, second paragraph, as allegedly being indefinite for reciting an improper Markush group, i.e., LDPE, HDPE, and PP should be listed in the alternative.

As amended herein, claims 13, 18, 23 and 29 recite LDPE, HDPE, and PP in the alternative, i.e., LDPE, HDPE or PP.

### **Claim Rejections - 35 USC § 103**

The Office Action has rejected claims 1-33 under 35 USC §103(a) as allegedly being unpatentable over Wong et al. (US 2002/0058049 A1) in view of Fehn (US 6,194,043) and Groeger (WO 01/51222 A1). Applicant respectfully disagrees.

The present invention as defined by the claims, distinguishes over Wong in view of Fehn and Groeger by claiming a packaged medicinal product having an extended shelf life, comprising a medicinal preparation contained within a plastic container having a fluorinated barrier layer on a surface of the body wall.

Wong does not teach or suggest any such packaged medicinal products. Instead, this reference teaches storing pharmaceutical compositions of prostaglandin-like-compounds in polypropylene containers.

Fehn does not cure the defects of Wong because this reference does not teach or suggest any packaged medicinal products as required by the claims. Instead, this reference

teaches storing food in post-consumer recycled (PCR) plastic containers having an interior film of fluorinated polyethylene to prevent contamination from the PCR plastic.

Groeger does not cure the defects of Fehn or Wong because this reference does not teach or suggest any packaged medicinal products contained within a plastic container having a fluorinated barrier layer on a surface of the body wall as required by the claims. Instead, this reference teaches that it is known in the art to use fluorinated polymers for lining the inner surfaces of aluminum canisters for storage and administration of medicaments.

Nor are the claims obvious over the cited references as a matter of obvious design choice. As described above, Fehn teaches using fluorinated polyethylene for lining the interior of PCR plastic food containers to prevent contamination from the PCR plastic; and Groeger teaches using fluorinated polymers for lining the inner surfaces of aluminum canisters for storage and administration of medicaments. Neither of these references teach or suggest using fluorinated polymers as containers for storing pharmaceutical compositions of prostaglandin-like-compounds, in place of polypropylene containers as taught by Wong. Nor do any of the cited references teach or suggest using a fluorinated barrier layer on the surface of a body wall of a plastic container to hold a medicinal preparation as required by the claims. Absent a teaching or suggestion in the prior art, one of skill in the art would not have been motivated to do what Applicant has claimed. Thus, the claims are not obvious over the cited references.

### **Conclusion**

Applicants believe that all claims are now in condition for allowance. Should there be any issues that have not been addressed to the Examiner's satisfaction, Applicants invite the Examiner to contact the undersigned attorney.

If any fees are due in connection with this response, including the fee for any required extension of time (for which Applicants hereby petition), please charge such fees to Deposit Account No. 500329.

Respectfully submitted,

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